

### **REMARKS**

The present Office Actions addresses and rejects claims 1-17. Reconsideration is respectfully requested in view of the following remarks.

#### ***Amendments to the Claims***

Claim 1 is amended to recite identifying a muscle plane "between muscles." This amendment is made in response to a §112 rejection, as noted below. No new matter is added.

#### ***Rejection Pursuant to 35 U.S.C. §112***

Claim 1 is rejected pursuant to 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner asserts that claim 1, line 5, recites "the muscles," but that there is no antecedent basis for this term. As noted above, claim 1 is amended to recite "identifying a muscle plane between muscles," thereby providing antecedent basis for "the muscles." This amendment therefore obviates the basis for this rejection.

#### ***Rejections Pursuant to 35 U.S.C. §102***

##### **Landry**

Claims 1 and 3 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Publication No. 2004/0143265 of Landry et al. ("Landry"). Applicants respectfully disagree.

Independent claim 1 recites a minimally invasive surgical method that includes forming an incision through tissue located adjacent to a vertebra in a patient's spinal column, identifying a muscle plane, and inserting a substantially planar blunt tip of a tool through the incision while manipulating the blunt tip along the muscle plane extending between the incision and the vertebra to separate the muscle.

Landry does not teach or even suggest inserting a blunt tip of a tool along a muscle plane *extending between an incision and a vertebra* to separate the muscle. Landry discloses a method for implanting a spinal stabilization system that includes locating an entry point in a vertebral body for a bone fastener using a targeting needle and inserting a guidewire through the targeting needle and into

bone. *See* paragraphs [0175] and [0177]. The guidewire is then used to receive tools, such as an awl or tap, to prepare a threaded passage for receiving a fastener. *See* paragraphs [0180]-[0183]. Once the threaded passage is prepared, a fastener is implanted. Landry does not teach or even suggest using any tool to separate a muscle plane extending between the *incision* and the *vertebra*. The targeting needle is simply penetrated through the tissue.

Landry does discuss forming a plane in soft tissue, however the plane does *not* extend from an incision to a vertebra, as required by claim 1. Instead, the plane extends *between two vertebrae*. In particular, Landry states that “[a] plane may be created in soft tissue between the first bone fastener assembly and a second pedicle.” Paragraph [0024]. Landry further explains that the fasteners implanted in the adjacent vertebrae can have a detachable sleeve (244) attached thereto, and the sleeve can include channels 248 that “may allow instruments to be positioned and used to form a plane through soft tissue to one or more adjacent vertebra.” Paragraph [0197]. “An elongated member may be inserted in the tissue plane and positioned in collars of bone fastener assemblies anchored in vertebrae and coupled to the sleeves.” *Id.* In other words, a spinal fixation rod is inserted along the plane to extend between two fastener assemblies. Accordingly, Landry only teaches forming a plane between two adjacent vertebrae.

Because Landry simply fails to teach manipulating a blunt tip along a muscle plane extending between an *incision* and a *vertebra* to separate the muscle, as required by claim 1, claim 1, as well as claim 3 which depends therefrom, distinguish over Landry and represent allowable subject matter.

Teitelbaum

Claims 11-17 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,821,277 of Teitelbaum. Applicants respectfully disagree.

Independent claim 11 recites a minimally invasive surgical method that includes making a first incision in a patient, inserting a blunt tip of a tool through the first incision and manipulating the blunt tip to create a first pathway from the first incision, between a muscle plane, to a first site on a first vertebral body, and advancing a guide wire through the tool to position a distal end of the guide wire adjacent the first site.

Teitelbaum does not teach or even suggest manipulating a blunt tip *between a muscle plane*. The Examiner argues that Teitelbaum teaches “making an incision in a patient (see Fig. 13, through the skin), inserting a blunt tip tool (202) through the skin to create a pathway between muscle.” While the pathway may extend through muscle, the pathway is certainly not *between a muscle plane*, as required by claim 11. Teitelbaum never even mentions the muscle, much less a muscle plane. To the contrary, Teitelbaum explains that the “bone biopsy needle or its equivalent is placed through the stab incision to create a tract to the posterior periosteal surface of the vertebrae . . . .” Accordingly, the needle simply penetrates directly through the muscle, and is not in any way manipulated between a muscle plane. Teitelbaum therefore fails to teach the claimed method.

Accordingly, claim 11, as well as claims 12-17 which depend therefrom, distinguish over Teitelbaum and represent allowable subject matter.

### ***Rejections Pursuant to 35 U.S.C. §103***

#### **Landry and Hamada**

Claim 2 is rejected pursuant to 35 U.S.C. §103(a) as being obvious over Landry in view of U.S. Patent No. 6,849,064 of Hamada. As explained above, Landry fails to teach or even suggest manipulating a blunt tip along a muscle plane extending between an *incision* and a *vertebra* to separate the muscle, as required by claim 1. Hamada does not remedy the deficiencies of Landry.

The Examiner argues that Hamada discloses access to a spinal area by separating the longissimus thoracis and multifidus muscles. This is incorrect. Hamada is directed to a single-entry device that expands to dilate tissue. As explained at Col. 9, lines 22-35, a discectomy is performed as follows:

A guide pin 155 is insert through the patient's skin 157, preferably under fluoroscopic guidance. In the alternative and or in combination, the patient 151 skin can be incised with a scalpel. Other features in FIG. 20 include the dural sac 159, and ruptured intervertebral disc 161.

Referring to FIG. 21, a fascial incisor 169 overfits the guide pin 155 and is further inserted to cut through external and internal tissue. The fascial incisor 169 is then removed while the guide pin 155 is left in place. Next, using the obturator 33, the surgeon clears the multifidus attachment

with wig-wag motion of the obturator 33 tip end. Next the obturator 33 is actuated to gently spread the multifidus muscle, and then closed.

Thus, according to the above passage, a guide pin is inserted to “cut though external and internal tissue.” Hamada never suggests identifying a muscle plane and manipulating a tool along the muscle plane extending between the incision and the vertebra to separate the muscles. The guide pin is simply penetrated directly through the muscles. Hamada does state that the obturator is moved to clear the multifidus attachment and to spread the muscle, but such movement of the obturator about the guide pin clearly does not constitute manipulating the tool along a muscle plane, since the guide pin is already penetrated through the muscle. A muscle plane is never identified and separated.

Accordingly, Hamada fails to remedy the deficiencies of Landry, and therefore claim 2 distinguishes over Landry and Hamada and represents allowable subject matter.

Landry and Teitelbaum

Claims 4-7 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Landry in view of Teitelbaum. As explained above with respect to claims 1 and 11, neither Landry nor Teitelbaum teach or even suggest manipulating a tool along a muscle plane extending between an *incision* and a *vertebra* to separate the muscle. Both Landry and Teitelbaum simply penetrate directly through the tissue between the incision and the vertebra without any regard to a muscle plane. Accordingly, because claim 1 distinguishes over Landry and Teitelbaum, claims 4-7 likewise distinguish over Landry and Teitelbaum at least because of their dependency on claim 1.

Landry, Teitelbaum, and Gitis

Claims 8-10 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Landry in view of Teitelbaum and further in view of U.S. Publication No. 2003/0216768 of Gitis. As explained above, neither Landry nor Teitelbaum teach or even suggest manipulating a tool along a muscle plane extending between an incision and a vertebra to separate the muscle, as required by claim 1. Gitis does not remedy the deficiencies of Landry and Teitelbaum. Gitis is directed to a plurality of cannulae and an obturator that are inserted over a guidewire that is penetrated *directly* through tissue. See paragraph [0049]. Gitis does not even mention identifying a muscle plane, much less inserting any type of tool along a muscle plane. Accordingly, because claim 1 distinguishes over Landry, Teitelbaum, and Gitis,

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claims 8-10 likewise distinguish over Landry, Teitelbaum, and Gitis at least because of their dependency on claim 1.

***Conclusion***

In view of the above, Applicant believes that all claims are in condition for allowance and allowance thereof is respectfully requested.

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